Translation

PCT/JP2003/014919

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C1-A0230P	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/014919	International filing date (*day/month/year*) 21 November 2003 (21.11.2003)	Priority date (*day/month/year*) 22 November 2002 (22.11.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/12, 15/09, C07K 16/32, 16/18, G01N 33/53		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21 November 2003 (21.11.2003)	01 April 2004 (01.04.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/014919

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/14919

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	12	YES
	Claims	1-11	NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations

Document 1: (Akihiro Abe), Report of Researches Sponsored by Sankyo Foundation of Life Science, 1998, Vol. 11, pages 213-219
Document 2: (Varsha Patki, et al.), Ann N Y Acad Sci, 1997, Vol. 815, pages 472-474
Document 3: (Howard Ratech), Biochemical and Biophysical Research Communications, 1992, Vol. 182, No. 3, pages 1260-1263
Document 4: JP, 6-141884, A (Yoshihide Hagiwara), 24 May, 1994 (24.05.94)
Document 5: (Shingo Ichinomiya, et al.), Annual Review Immunity 2002, 2001, pages 147-179
Document 6: (Lin Luo, et al.), Nature Medicine, 1999, Vol. 5, No. 1, pages 117-122
Document 7: (Tetsuhiko Tachikawa, et al.), Hematology and Oncology, 2001, Vol. 42, No. 6, pages 565-571

Claims 1-11

The subject matters of claims 1-11 do not appear to be novel in view of document 1.

Document 1 describes that RNA was extracted from leukemia cells of patients with B cell lymphocytic leukemia, the VH region of the idiotype genes was amplified and integrated into plasmid by means of the RT-PCR method (pLV_HRNL), whereby the region was expressed in *Escherichia coli*, and that pLV_HRNL was administered to mice.

Claims 1 and 3-6

The subject matters of claims 1 and 3-6 do not appear to be novel in view of document 2.

Document 2 describes that RNA was extracted from B lymphocytes of patients with rheumatism and a group of DNA fragments of IgV_H genes was obtained.

Claims 1-12

The subject matters of claims 1-12 do not appear to involve an inventive step in view of documents 1-7.

Document 3 describes that a group of DNA fragments of IgV_H genes was obtained from B cells.

Document 4 describes the amino acid sequence and base sequence of the variable region of H and L chains of human immunoglobulin IgG specific for a cancer cell antigen produced by human/human fused-cell strains made from B cells of patients with uterine cancer and human lymphoblast cell strains.

It was known from documents 4-7 before the priority date of the present application that specific targeted lesion cells are cut out by means of LCA. Particularly, document 5 describes that cancer tissues or B cells are taken by means of LCA, etc. for gene analysis. Accordingly, a person could have easily conceived of the idea of taking only targeted cancer cells by means of LCA, etc., obtaining genes to code for an antigen that is expressed specifically in cancer cells, and allowing the said antigen to express in host cells, whereby such antigen responding specifically to cancer is obtained.

The effects of the subject matters of claims 1-12 do not appear to be beyond expectation.